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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/439,040 11/12/99 VAN DONGEN

J 4222US

HM22/0619

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EXAMINER

WILDER, C

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

06/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/439,040

Applicant(s)

Van Dongen et al.

Examiner

CB Wilder

Group Art Unit

1655

☒ Responsive to communication(s) filed on Nov 12, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-12 and 14-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-12 and 14-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: EP 97201440.1

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in European Patent Office EP 97201440.1 on 05/13/1997. It is noted, however, that a certified copy of the application has not been provided with the instant application serial number 09/439,040 filed 11/12/1999. Therefore, priority has not been granted for EP 97201440.1 filing date 05/13/1997.

Claim Objections

2. Claim objected to because of the following informalities:

- (a) The word "hybridise" is misspelled in claims 3, 6, 9, 10, 17 and 20. It is suggest changing "hybridise" to "hybridize" . Appropriate correction is required.

Claim Rejections - 35 USC § 112 second paragraph

3. Claims 10-12, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- (a) Claim 10 is indefinite for "under low-stringent conditions" because the hybridization conditions have not been defined in the specification or claims and it cannot be determined what conditions are

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necessary for hybridization of the probes to the DNA molecules. It is suggested to amend the claims to include the hybridization conditions.

(b) Claims 11, 12, 14 and 15 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted element is steps that describe how the claimed method is performed in order to analyze a sample for chromosomal aberration. Clarification is required.

Claim Rejections - 35 USC § 112/101

4. Claim 11 provides for the use of the pair of probes of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102(b)

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12, 14, 15, and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Tkachuk et al. (Tkachuk, herein) (Science October 1990). Regarding claim 1, Tkachuk discloses a pair of nucleic acid probes having comparable size, said size being from about 10-30 kb in size, and flanking a potential breakpoint in a chromosome, each said probe being labeled with at least one different reporter molecule (page 560, "Figure 1" and col. 1, lines 5-7, 13-15 and 22-27).

Regarding claims 2 and 3, Tkachuk discloses a pair of nucleic acid probes comparable size, said size being from about 10-30 kb and flanking a potential breakpoint in a chromosome, which pair of nucleic acid probes hybridize to a nucleic acid molecule at a genomic distance of less than 250 kb or about 25 to 225 kb (page 560, "Figure 1" and col. 3, lines 2-8). See also *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)).

Regarding claims 4 and 5, Tkachuk teach wherein the pair of nucleic acid probes are labeled indirectly with at least one reporter molecule and wherein the reporter molecule is a fluorochromes (page 560, col. 1, lines 22-27).

Regarding claims 7-8, and 19-21, Tkachuk teach wherein the nucleic acid probes hybridize to a single corresponding nucleic acid molecule and wherein the single corresponding nucleic acid

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molecule is at least a fragment of a chromosome and wherein the chromosome is not aberrant (normal) and aberrant (CML) (page 561, "Figure 3").

Claim 9 is drawn to a pair of nucleic acid probes of claim 1 which hybridize *in situ*. Tkachuk discloses wherein fluorescent *in situ* hybridization was carried out using the probes as described previously (page 560, col. 1, lines 22-27).

Regarding claim 10, Tkachuk discloses wherein the pair of probes hybridizes *in situ* under conditions to only a few linear DNA molecules per cell (page 560, "Figure 1").

Regarding claim 11, Tkachuk discloses a method of detecting a nucleic acid molecule having a chromosomal aberration said method comprising using pair of probes as discussed previously to analyze a sample believed to contain nucleic acid (page 559, "Abstract").

Regarding claim 12, Tkachuk discloses a method of detecting cells suspected of having a chromosomal aberration, said method comprising analyzing said cell with the pair of nucleic acid probes as described previously (page 559, col. 3, lines 19-23 and page 560, col. 1, lines 1-3 and 31-41).

Regarding claims 14 and 15, Tkachuk discloses wherein the chromosomal aberration is associated with hematopoietic malignancy (page 559, "Abstract").

Regarding claims 17 and 18, Tkachuk discloses wherein the probes hybridize to a single corresponding nucleic acid molecule and wherein the single chromosome molecule is at least a fragment of a chromosome (page 561, "Figure 3").

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Therefore, the claimed invention of claims 1-12, 14, 15, and 17-21 are anticipated by the reference of Tkachuk.

7. Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Rowley et al. (Rowley, herein) (5,487,970 January 30, 1996). Claim 16 is drawn to a diagnostic kit comprising at least the pair of nucleic acid probes of claim 1. Rowley teaches a diagnostic kit comprising a pair of nucleic acid probes having comparable size wherein the size is from about 0.3 kb to 1.5 kb, and labels for the probes for *in situ* hybridization procedures (col. 7, lines 19-44). Therefore, the claimed invention of claim 16 is anticipated by the reference of Rowley.

Prior Art

8. The prior art is considered pertinent to applicant's disclosure. Russo et al. (WO 94/24308 October 27, 1994) teach probes having comparable size used to detect chromosome aberration wherein the probes are at least 10 or 20 kb or between 40 and 100 kb (page 5, lines 32 and 33, page 14, claims 4 and 7).

Conclusion

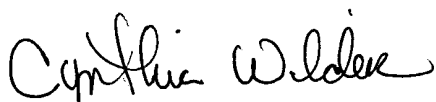
9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the Exr. should be directed to Exr. Cynthia Wilder whose telephone number is (703) 305-1680. The Exr. can normally be reached on Monday through Thursday from 7:00 am to 5:00 pm.

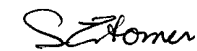
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If attempts to reach the Exr. by telephone are unsuccessful, the Exr.'s supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.


Cynthia B. Wilder, Ph.D.

June 16, 2000


STEPHANIE G. ZIMMER
PRIMARY EXAMINER